## Judy Cox Westra MS/RD/LD

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May 23, 1999

Docket Management Branch (HFA-305) 5630 Fishers LN RM 1061 Rockeville, MD 20857-0003

Dear Director:

I as a consumer of healthcare provider services would like to bring to your attention the need to change some of the writing of the rule for the Compounding section 503A of the Modernization Act. I personally, because of complex allergies have been for several years receiving medical attention from a specialist in allergies and receive allergy shots and a hormone from a different state than I reside. These medications are vital for my survival to be able to breath and lessen my episodes of allergic reactions. I have several sensitivities to many drugs and in my past medical history have had some severe reactions, but for 15 years have been able to tolerate several alternative medications that I assisted me with my health and actually have improved my allergies. The wording of this proposed rule does not take into consideration cases such as myself which do not fit into the majority of the population. This law infringes on my patient rights and my physcian's judgment to obtain healthcare from the provider of my choice and prescribe the medication that will assist in my health and welfare. As a patient there should be no restrictions to how my medications are compounded or delivered regardless of where I may live or travel. Therefore I am requesting that the MOU be amended.

The FDA is a agency of the U.S. government that purpose is to be a watchdog for the consumer safety. This is not a safety issue. As a government agency the FDA also has the responsibility to be accountable to all the citizens and not just the majority of the population; therefore as a agency I ask you to rethink this section of the law and amend the MOU section of this law.

Sincerely:

Judy Cox Westra MS/RD/LD

cc: Sentator Pete Domenici, Jeff Bingham,

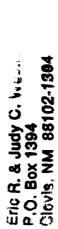
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U.S. House of Representative Heather Wilson, Joe Skeen and Tom Udhall

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